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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
MORRIS, PATRICIA L	

ART UNIT	PAPER NUMBER
1625	

DATE MAILED: 05/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/941,001	SANNER ET AL.	
	Examiner	Art Unit	
	Patricia L. Morris	1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 March 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-43* is/are pending in the application.

4a) Of the above claim(s) *3,17-24 and 27-43* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4-16,25 and 26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1, 2, 4-16, 25 and 26 are under consideration in this application.

Claims 3, 17-24 and 27-43 are held withdrawn from consideration as being drawn to nonelected subject matter 37 CFR 1.142(b).

Election/Restrictions

Applicant's election with traverse of Group I, the compound N[5-(cis-3-acetylaminocyclobutyl)-IH-pyrazol-3-yl]-2-naphthalen-1-yl-acetamide and the method of treating Alzheimer's disease in the response filed March 19, 2004 is acknowledged. The traversal is on the ground(s) that the inventions are not patentably distinct. This is not found persuasive because for the reasons clearly set forth in the Office action mailed January 12, 2004. Further, applicants have failed to advance any cogent reasons as to why the inventions are not patentably distinct. The prior art of record clearly shows that applicants are merely claiming compounds in the art and fail to make any contribution to the prior art. Applicants assert that they fail to understand that a species election was imposed. Applicants are invited to note the bridging paragraph on pages 3-4 of the previous Office action where the requirement is clearly set forth therein.

The requirement is still deemed sound and proper and is therefore maintained.

Claims 16, 25 and 26 are examined to the extent readable on the treatment of Alzheimer's disease, exclusively.

This application has been examined with regard to the **elected species** wherein R^1, R^7, R^{10} and R^{11} represent non-heterocyclic groups, R^4 is $(C_6\text{-}C_{14})$aryl (optionally substituted by

nonheterocyclic groups), R^3 is $-CO(CR^{10}R^{11})_n$, n is 0-3 and R^2 as set forth in claim 1, exclusively.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 2, 4-16, 25 and 26 are rejected under 35 U.S.C. 102(a), (b) and/or (e) as being anticipated by Pervarello et al (US 6,218,418), Ferruccio et al. (US 6,020,498), Malle et al. (US 6,118,008), Lepage et al. (US 5,464,860), Daidone et al. I (CA 105:39189), II (CA 125:195490), III (CA 104:17558), Sato (CA 127:358859), Burow (US 4,515,625) and Seki et al. (US 4,505,739).

Pervarello et al. specifically disclose the instant compounds having the same use wherein R^1 is a cycloalkyl, R^2 is hydrogen, n is 0 or 1 and R^4 is aryl. Note the specific reference compounds recited in columns 6-9 therein.

Ferruccio et al. specifically disclose N-[5-(1,-dimethylethyl)-1H-pyrazol-3-yl]-4-nitro-benzamide. Note example 3 therein.

Malle et al. recite N-(5-methyl-1H-pyrazol-3-yl)-benzamide. Note example 2 therein.

Leparge et al. disclose the claimed compounds wherein R^1 is alkyl, R^2 is hydrogen, n is zero and R^4 is phenyl substituted by alkyl. Note, for example, compound no. 1 therein.

Daidone et al. I, II, III and Sato disclose the instant compounds wherein R^1 is methyl or t-butyl and R^4 is phenyl substituted by nitro or hydroxy. Note RN 103060-68-0 of Daidone et al. I or RN 180691-50-3 of Daidone et al. II and RN's 98817-27-7 or 98817-29-9 of Daidone et al. III or RN 198628-44-3 of Sato.

Burrow specifically recite the instant compounds wherein R^1 is alkyl, R^2 is hydrogen, n is zero and R^4 is phenyl substituted by methoxy. Note examples 114-117 therein.

Seki et al. teach the instant compounds wherein R^1 is t-butyl, R^2 is hydrogen, n is one and R^4 is phenyl.

Hence, the instant compounds are deemed to be anticipated therefrom.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 2, 4-16, 25 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined teachings of Pervarello et al., Ferruccio et al., Malle et al., Lepage et al., Daidone et al. I-III, Sato, Burow and Seki et al.

As discussed supra, the references generically embrace the instant compounds having the same use. Note, for example, the compounds in columns 6-9 of Pervarello et al., example 3 of Ferruccio et al. or example 2 of Malle et al.

It is believed that one having ordinary skill in the art would have found the claimed compounds *prima facie* obvious, since they are generically embraced by the disclosed formula; In re Susi, 440 F.2d 442, 169 USPQ 423 (CCPA 1971). See also In re Malagari, 499 F.2 1297, 182 USPQ 549 (CCPA 1974); In re Lemin, 332 F.2d 839, 141 USPQ 814 (CCPA 1964); In re Rosicky, 276 F.2d 656, 125 USPQ 341 (CCPA 1960). The requisite motivation for arriving at the claimed compounds stems from the fact that they fall within the generic class of compounds disclosed by the references. Accordingly, one having ordinary skill in the art would have been motivated to prepare any of the compounds embraced by the disclosed generic formula, including those encompassed by the claims, with the expectation that each of them would be suitable for the treatment of Alzheimer's disease.

It is believed well settled that a reference may be relied upon for all that it would have reasonably conveyed to one having ordinary skill in the art. In re Fracalossi, 681 F.2d 792, 215 USPQ 569 (CCPA 1982); In re Lamberti, 545 F.2d 747, 192 USPQ 278 (CCPA 1976); In re Rinehart, 531 F.2d 1048, 189 USPQ 143 (CCPA 1976); In re Susi, supra.

Further, the references teach compounds that differ from the compounds herein as being homologs. For example, the instant compounds wherein R^1 is cyclobutyl are just the next adjacent homologs of the cylopropyl compounds of Pervarello or the compounds wherein R^1 is propyl , n-butyl or iso-butyl and pentyl are homologs of the t-butyl compound of Ferruccio. One having ordinary skill in the art would have been motivated by the disclosure of the prior art compounds to arrive at the instant compound. The motivation to make the instant compounds is their close structural similarities to the disclosed compounds. Note that the disclosed compounds are useful for the treatment of Alzheimer's disease, thus the skilled artisan would expect such structurally similar compounds to possess similar properties. While homology is considered to be present even if true "homology" is not present, such does not defeat the prima facie case of obviousness raised by the art. Attention, in this regard is directed to In re Druey et al., 50 CCPA 1538, 319 F.2d 237, 138 USPQ 39, wherein Judge Worley, delivering the Court"s opinion, stated:

> We need not decide here whether the compounds in question are properly labeled homologues. It appears to us from the authorities cited by the solicitor and appellants that the term homologue is used by chemists at times in a broad sense, and at other times in a narrow or strict sense. The name used to designate the relationship between the related compound is not necessarily controlling; it is the closeness of that relationship which is indicative of the obviousness or unobviousness of the new compound. 50 CCPA 1541.

Also, as the Court stated in In re Payne et al., 606 F.2d 302, 203 USPQ 245 at 255 (CCPA 1979):

> The name used to designate the relationship between related compounds is not necessarily controlling; it is the closeness of that relationship which is indicative of the obviousness or unobviousness of the new compound."

In addition, any question of why would one conceive and use the similar compounds (*i.e.* motivation is answered by the Court in In re Gyurik et al., 596 F.2d 1012, 201 USPQ 552 at 557.

> In obviousness rejections based in close similarity in chemical structure, the necessary motivation to make a claimed compound, and thus the *prima facie* case of obviousness, rises from the expectation that compounds similar in structure will have similar properties.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is undue. These factors include 1) the breadth of the claims, 2) the nature of the invention, 3) the state of the prior art, 4) the level of one of ordinary skill, 5) the level of predictability in the art, 6) the amount of direction provided by the inventor, 7) the existence of working examples, and 8) the quantity of experimentation needed to make or use the invention based on the content of the disclosure. In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

No enablement is shown for the treatment of Alzheimer's disease. The specification lacks any *in vitro* or *in vivo* tests. There are no working examples anywhere in the specification.

The disclosure provides no indication of whether the compounds treat any Alzheimer's disease.

The claims require undue experimentation on the part of the reader to determine which compound (at what host - dosage relationship) has utility against Alzheimer's disease.

Applicants' disclosure fails to provide a description of a method of treating or inhibiting any diabetic condition in a single infected host. Methods of treating a specific condition with a active agent, whether old or new, should be enabled by a specification containing a statistically significant example, which should include the organism treated. Applicants have not provided such a disclosure. Moreover, applicants" statements with regard to the various dosages and modes of administration of the instant compounds, for the treatment of Alzheimer's disease are merely speculative, since nowhere in the specification as filed, is described a method of treating or inhibiting any Alzheimer's disease, *in vivo* in a single patient.

Thus, applicants' situation is much like that of In re Kirk, 153 USPQ 48: "What the applicants are really saying to those skilled in the art is take these compounds experiment, and find out what use they have. Undue experimentation would be required.

Claims 1, 4, 5 and 8-12 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The expression optionally substituted is employed in claims 1, 4, 5 and 8-12 with no indication given as to what the substituents really are for the variables R^1 and R^4.

One should be able, from a reading of the claims, determine what that claim does or does not encompass.

Why? Because that claim precludes others from making, using, or selling that compound for 20 years. Therefore, one must know what compound is being claimed.

The unknown substituents are so broad that they cause the claim to have a potential scope of protection beyond that which is justified by the specification disclosure.

The written description is considered inadequate here in the specification. Conception of the intended substituents should not be the role of the reader. Applicants should, in return for a 20 year monopoly, be disclosing to the public that which they know as an actual demonstrated fact. The disclosure should not be merely an invitation to experiment. This is a 35 USC 112, first paragraph. If you (the public) find that it works, I claim it, is not a proper basis of patentability. In re Kirk, 153 USPQ 48, at page 53.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 7, 15, 16 and 26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The variables R^5 and R^6 defined in claim 1 are not set forth in the structure.

Claim 7 lacks antecedent basis because the substituents defined for R^1 are not found in claim 1.

The plural "s" on salts in claim 15 is indefinite to its meaning because it allows for the inclusion of mixtures.

Regarding claim 26, the phrase "for example" renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Claim 16 provides for the use of the treatment of Alzheimer's disease but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim16 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia L. Morris whose telephone number is (571) 272-0688.

The examiner can normally be reached on Mondays through Fridays.The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Patricia L. Morris
Primary Examiner
Art Unit 1625

plm
May 14, 2004